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10/696,699	10/29/2003	Bob G. Sanders	D6453CIP	7495

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EXAMINER	
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ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 05/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/696,699	SANDERS ET AL.	
	Examiner	Art Unit	
	F. Pierre VanderVegt	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10 and 39-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10 and 39-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *04042005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This application is a continuation-in-part of U.S. Application Serial Number 10/419,629, which claims the benefit of the filing date of provisional application 60/373,870.

Claims 1-9 and 11-38 have been canceled.

New claims 39-48 have been added.

Claims 10 and 39-48 are currently pending.

Election/Restrictions

1. Applicant's election without traverse of Group III, claim 10, drawn to tocopherol associated protein p38, in the reply filed on February 27, 2006 is acknowledged.

It is noted that Applicant has canceled all claims not directed to the non-elected invention and added new claims 39-48, all of which read upon the elected invention.

Accordingly, **claims 10 and 39-48 are the subject of examination** in the present Office Action.

Claim Objections

2. Claim 45 is objected to because of the following informalities: The claim recites "TAP-881," which is a term not disclosed in the specification. It is believed that this is a typographical error and that the claim was intended to recite the polypeptide of "TAP-882."

Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 43, 44 and 48 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a NEW MATTER rejection.

New claims 43, 44 and 48 were introduced in the amendment filed February 27, 2006. All claims are drawn to an antibody that binds to the TAP-38 polypeptide of SEQ ID NO: 2, reciting additional limitations upon the antibody. Disclosure in the specification regarding antibody to TAP-38 can be found at page 8, line 15 through page 9, line 2, where it is disclosed that polyclonal rabbit antibodies that bind to TAP-38 were raised using an antigen consisting of SEQ ID NO: 8, corresponding to the C-terminal 16 amino acids of TAP-38, TAP-46 and the deletion mutants TAP-882, TAP-681 and TAP-456. the only other disclosure of antibody to TAP-38 is found in the recitation, " The present invention is also directed to an antibody directed against the tocopherol associated protein p38 described herein" at page 15, lines 4-6.

Claim 43 recites that the claimed antibody is a monoclonal antibody. However, there is no disclosure in the specification of a monoclonal antibody and the above-cited recitations from the specification do not provide adequate support for the limitation in the claim. While the production of monoclonal antibodies to a polypeptide is a routine practice in the art and may be considered obvious by the practitioner, Applicant is reminded that obviousness is not the standard for the addition new limitations to the disclosure as filed. Entitlement to a filing date does not extend to subject matter that is not disclosed, but would be obvious over what is expressly disclosed. Lockwood v. American Airlines Inc., 41 USPQ2d 1961 (Fed. Cir. 1977).

Claim 44 recites that the claimed antibody binds to denatured TAP-38. However, as above, the above-cited recitations from the specification do not provide adequate support for the limitation in the claim.

Claim 48 recites that the claimed antibody "binds to the 30 unique amino acids of TAP-38. There is no support for this limitation in the specification. The specification discloses only antibodies that were raised to the 16 C-terminal amino acid residues of TAP-38 (pages8-9) and that the invention includes an antibody to TAP-38 (page 15). Other than said C-terminal region, there is no disclosure of antibodies to any particular domain or fragment of TAP-38. Furthermore, there is not even a generic disclosure of an antibody to a fragment of TAP-38. Simply reciting that antibodies to a polypeptide are part of an invention and separately in the specification identifying a particular region of that polypeptide as being of interest is not adequate disclosure to claim specific antibodies to that region.

Vas-Cath Inc. v. Mahurkar ((CAFC, 1991) 19 USPQ2d 1111), clearly states that "Applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See *Vas-Cath* at page 1117). The specification does not "clearly allow persons of ordinary

skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see *Vas-Cath* at page 1115).

5. Claim 48 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether undue experimentation is required are summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986). They include the nature of the invention, the state of the prior art, the relative skill of those in the art, the amount of direction or guidance disclosed in the specification, the presence or absence of working examples, the predictability or unpredictability of the art, the breadth of the claims, and the quantity of experimentation which would be required in order to practice the invention as claimed.

A literal interpretation of the claim reads on encompassing a single antibody that binds to all 30 of the "unique" amino acid residues of TAP-38. Since it is well known in the art that an antibody typically binds to an epitope consisting of a 5-6-mer of amino acids, one of skill in the art cannot envision how to produce an antibody that binds to 30 amino acid residues. Furthermore, even if one knew how to make an antibody with a binding site that binds to 30 amino acid residues, one would not expect that it would be possible to conduct an immunization that would result in the production of an antibody that would recognize these particular 30 "unique" amino acids. since there is no teaching that the TAP-38 folds in 3-dimensions to bring these 30 "unique" amino acids in close proximity to one another, one would not know how to immunize with TAP-38 in order to produce what is claimed, as sequence matching of TAP-38 as disclosed with TAP-46 shows that there is identity of several amino acid residues within the region of 30 "unique" amino acid residues.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 48 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 48 is ambiguous in the recitation of "antibody of claims 10" in line 1. The claim recites only a single claim upon which it is dependent.

Claim 48 is further ambiguous and unclear in the recitation of "antibody binds to the 30 unique amino acids of TAP-38." It is not clear what the "unique"30 amino acids are being compared to. If the claim is referring to a region that differentiates the sequence of TAP-38 from TAP-46, Applicant should more positively recite the distinguishing region in a manner commensurate with the disclosure in the specification. Simply reciting "30 unique amino acids of TAP-38" invites comparison of any 30 amino acids of TAP-38 to any polypeptide sequence that differs over a given 30 amino acid region from TAP-38.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 10 and 39-48 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by U.S. Patent Application Publication 2004/0023227 A1 of Inoue et al. (filed August 30, 2002 with priority to PCT/JP01/01592 filed March 1, 2001; A on form PTO-892).

The claims are drawn to antibodies to TAP-38 as defined by the 378 amino acid sequence of SEQ ID NO: 2. It is noted that TAP-38 is derived from the amino acid sequence of TAP-46 (instant SEQ ID NO: 4), having 27 amino acid substitutions and 25 amino acid deletions from the 403 amino acid sequence of TAP-46. All of the deletions and all but two of the substitutions occur between amino acid residues 18 and 74 of TAP-46 (SEQ ID NO: 4). Amino acid residues 1-18 of TAP-38 are identical to residues 1-18 of TAP-46 and residues 49-378 of TAP-38 are 99.38% identical to residues 74-403 of TAP-46. Dependent claims further claim anti-TAP-38 antibodies that are cross-reactive with TAP-46 [claim 39] and the truncation mutants of TAP-46 disclosed as TAP-881 [treated here as meaning TAP-882, claim 45], TAP-681 [claim 46], and TAP-456 [claim 47].

The '227 A1 publication teaches human squalene epoxidase-promoting factor (SPF), a 403 amino acid polypeptide disclosed as SEQ ID NO: 4 that is 100% identical to instant TAP-46 (Figure 2 in particular). The '227 A1 publication teaches the generation of polyclonal (claim 41], rabbit [claim 42] and monoclonal [claim 43] antibodies to human SPF (paragraphs **[0033] - [0036]** in particular). Given that human SPF of the '227 A1 publication is identical to the instantly disclosed TAP-46, it is readily apparent that antibodies raised to human SPF will inherently bind to TAP-46. Furthermore, given the high identity of Tap-38 to TAP-46 (and therefore human SPF) over long sequences, immunization of an animal with human SPF would inherently generate antibodies that bind to TAP-38.

TAP-881 [treated here as meaning TAP-882, recited in claim 45] is identical to amino acid residues 111-403 of human SPF. Immunization of an animal with human SPF would inherently generate antibodies that bind to TAP-881 (TAP-882).

TAP-681 [recited in claim 46] is identical to amino acid residues 178-403 of human SPF. Immunization of an animal with human SPF would inherently generate antibodies that bind to TAP-681.

TAP-456 [recited in claim 47] is identical to amino acid residues 253-403 of human SPF. Immunization of an animal with human SPF would inherently generate antibodies that bind to TAP-456.

The prior art teaching clearly anticipates the claimed invention.

Claim 48 is included because the metes and bounds of the "30 unique amino acids of TAP-38" are not set forth in the claim. Accordingly, antibodies raised to human SPF will bind to 30 amino acid regions of TAP-38 that are unique when compared to polypeptides unrelated to human SPF or TAP-38.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 10, 39, 40 and 43-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Collins et al (NCBI EntrezProtein Accession code:CAB51405, July, 1999; U on form PTO-892) in view of Campbell (Monoclonal Antibody Technology [1985] pages 1-32; V on form PTO-892).

Collins teaches a cDNA sequence submitted to the EMBL/GenBank/DDBJ databases and the corresponding 403 amino acid polypeptide encoded by said cDNA. The polypeptide taught by Collins is 100% identical to TAP-46 (SEQ ID NO: 4).

Collins does not teach antibodies to the polypeptide.

Given that the Collins polypeptide is identical to the instantly disclosed TAP-46, it is readily apparent that antibodies raised to human SPF will inherently bind to TAP-46. Furthermore, given the high identity of Tap-38 to TAP-46 (and therefore human SPF) over long sequences, immunization of an animal with the Collins polypeptide would inherently generate antibodies that bind to TAP-38.

TAP-881 [treated here as meaning TAP-882, recited in claim 45] is identical to amino acid residues 111-403 of the Collins polypeptide. Immunization of an animal with the Collins polypeptide would inherently generate antibodies that bind to TAP-881 (TAP-882).

TAP-681 [recited in claim 46] is identical to amino acid residues 178-403 of the Collins polypeptide. Immunization of an animal with the Collins polypeptide would inherently generate antibodies that bind to TAP-681.

TAP-456 [recited in claim 47] is identical to amino acid residues 253-403 of the Collins polypeptide. Immunization of an animal with the Collins polypeptide would inherently generate antibodies that bind to TAP-456.

The prior art teaching clearly anticipates the claimed invention.

Claim 48 is included because the metes and bounds of the "30 unique amino acids of TAP-38" are not set forth in the claim. Accordingly, antibodies raised to the Collins polypeptide will bind to 30 amino acid regions of TAP-38 that are unique when compared to polypeptides unrelated to the Collins polypeptide or TAP-38.

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to make monoclonal antibodies specific for the polypeptide taught by Collins. One would have been motivated, with a reasonable expectation of success, to generate mAbs to the polypeptide based on the teachings of Campbell that it is a conventional practice in the art.

Conclusion

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (571) 272-0852. The examiner can normally be reached on M-Th 6:30-4:00 and Alternate Fridays 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

F. Pierre VanderVegt, Ph.D. RV
Patent Examiner
May 10, 2006

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